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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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08/346,910 11/30/94 LIPTON

00108017004

EXAMINER

ART UNIT	PAPER NUMBER
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DATE MAILED: 1812

09/04/96

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on 5/6/96, 5/29/96, & 8/9/96
- ☒ This action is FINAL.

- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire _____ month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2-10 is/are pending in the application.
- Of the above, claim(s) 2-7 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 8-10 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claims _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☒ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

- SEE OFFICE ACTION ON THE FOLLOWING PAGES -

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Part III DETAILED ACTION

Response to Amendment

1. Applicants' election of Group I, claim 1, in Amendment B, Paper No. 8, filed 5/6/96, is acknowledged. Claim 1 has been cancelled. New claims 8-10 have been added. Because Applicants did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (M.P.E.P. § 818.03(a)). Claims 2-7 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected group. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Any objections or rejections made in a previous Office Action that are not herein reinstated have been withdrawn.
3. The specification remains objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure for reasons of record and for the following reasons. Applicants' arguments filed 5/6/96 have been fully considered but they are not deemed to be only partially persuasive. The Examiner agrees with Applicant that Clone TR2B, now known as ATCC Deposit No. 97525, has been ligated to a vector well known in the art, lambda gt11. However, the Examiner respectfully disagrees

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with Applicant that those of skill in the art could use the invention once the deposit was obtained. Although it is true that the restriction enzyme EcoR1 could excise the claimed cDNA from the plasmid, the skilled artisan still cannot use the invention because it is not adequately described by the specification. The Examiner maintains his position that in order to use the claimed nucleic acid, the sequence of the nucleic acid must be known (described) or antibodies that can detect the protein it expresses must be publicly available for reasons of record and the following. The disclosure states that "Applicants have found that protein 68075 [the protein encoded by the coding regions of the nucleotide sequence deposited in ATCC Deposit No. 97525] of mammals enhances the regeneration of nerve cell processes in vivo in humans" (page 5, lines 23-25). Since Applicants have explicitly stated that they have observed the effects of protein 68075 in humans, the Examiner invites Applicants to present information to overcome the objection to the specification by submitting a declaration that provides some details of how protein 68075 can be detected or isolated prior to its use in humans without either: a) knowing the nucleic acid sequence that encodes protein 68075 (found in ATCC Deposit No. 97525) or the amino acid sequence of protein 68075 itself or b) using the anti-idiotypic antibodies TEPC-15 and HOPC-8, which do not appear to be available to the general public, to detect

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and/or isolate protein 68075, which is encoded by the claimed invention. The Examiner believes that without at least one of these two requirements, the skilled artisan cannot use the invention because the claimed nucleic acid sequence which expresses a protein for neural regeneration cannot be monitored for its functional expression of the encoded protein once it is excised from the lambda gt11 vector. It cannot be monitored for its functional expression of the encoded protein because there is no way to detect the successful expression of this protein by antibodies or by sequencing because a) the antibodies are not publicly available and b) the sequences are not taught by the disclosure. Without being able to monitor for the functional expression of the protein, the skilled artisan would not be able to predict if the protein was being produced in any system he chose to express the protein in, or if the nucleic acid sequence was inserted in the wrong direction, digested by enzymes, transcriptionally or translationally inhibited, not inserted into the expression system at all, or any of the other reasons commonly known in the art for the failure of a recombinant protein to be expressed from its encoding nucleic acid. Simply being able to hybridize the claimed nucleic acid to itself, or to hybridize the claimed nucleic acid to other nucleic acids does not enable the skilled artisan to predict if the nucleotide sequence is being functionally used to produce protein because

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the hybridization occurs independently of the production of the encoded protein. If the protein is not expressed by the claimed nucleic acid, then the skilled artisan cannot use the claimed nucleic acid, or sequences which hybridize to it, or fragments of the claimed sequence, because the claimed nucleic acid sequence cannot be used by the skilled artisan except for the neural regeneration that Applicant alleges, but does not adequately describe nor provide sufficient examples or guidance pertaining to the use of the claimed nucleic acid without at some point needing to know its sequence or be in possession of antibodies against the expressed protein.

The disclosure also does not provide an adequate written description, guidance, or examples for the skilled artisan to use the claimed nucleic acids without some way of detecting positive clones expressing the protein, thereby allowing their selection for protein production. The specification does not support the use of the claimed nucleic acids in vivo because of the extreme difficulty known in the art of gene therapy of making adequate vectors that are capable of efficient transfection and sustained expression of desired products for their therapeutic effects. The portions of the specification that describe the use of the claimed nucleic acids for in vivo genetherapy use are merely prophetic and cannot put the claimed invention into the hands of the skilled artisan.

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4. Claims 8-10 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

5. Claims 8 is rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 8 recites "ATCC 94525" when it appears that --ATCC 97525-- was intended. Appropriate correction is required.

6. It is believed that all pertinent arguments have been addressed.

7. No claim is allowed.

8. Applicant's amendment necessitated the new grounds of rejection. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen

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Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Friday from 0800 to 1630.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stephen Walsh, can be reached on (703) 308-2957. The fax phone number for this Group is (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

SG
Stephen Gucker

September 3, 1996

Stephen Walsh
STEPHEN G. WALSH
PRIMARY EXAMINER
GROUP 1800